

**REMARKS**

Claims 1-8 are pending. Claim 1 has been amended and claim 9 has been canceled. No new matter has been added by this amendment.

A supplemental IDS will be submitted shortly.

**Specification**

The specification has been amended at page 1, lines 3-5, to update the status of United States Application Number 09/472,657.

**Claim Objections**

Claim 1 has been amended to address the Examiner's objections.

**Claim Rejections – 35 USC § 102**

The Examiner rejected claims 1-8 under 35 USC § 102(e) as being anticipated by Duong (US Patent No. 6,740,518 B1). Without admitting the propriety of the rejection and reserving the right to pursue the broader claims in continuing applications, claim 1 has been amended.

Amended claim 1 now recites applying an initiation signal to an electrode within an evacuated tube. Because the Examiner admits that Duong does not disclose a tissue collection device comprising an evacuated tube (Office Action dated 04/06/2005, p. 6, 3rd paragraph), Duong does not disclose each and every limitation of claim 1 and claims 2-8 dependent therefrom. Applicants thus respectfully request that the Examiner withdraw the rejection of claims 1-8 under 35 USC § 102(e).

**Claim Rejections – 35 USC § 103**

The Examiner rejected claim 9 under 35 USC § 103(a) as being unpatentable over Duong in view of Furse (US Patent No. 5,354,483). Claim 9 has been canceled and claim 1 has been amended to incorporate the limitations of claim 9.

The Examiner asserts that the motivation for making a tissue collection device comprising an evacuated tube is given by Furse, which teaches certain advantages for using evacuated tubes to contain blood.

To establish a *prima facie* case for obviousness, the Examiner is required to show suggestion or motivation to modify a reference or to combine reference teachings. Furse does not suggest that an evacuated tube can or should be used in a method for detecting a target analyte; rather, it merely states the general advantages of an evacuated tube for containing blood. The Federal Circuit has rejected relying on statements regarding the general advantages of a component to provide the suggestion or motivation to combine references. See *Gillette Co. v. S.C. Johnson & Son, Inc.*, 919 F.2d 720, 726 (Fed. Cir. 1990) (“We reject Gillette’s remaining argument that other art-recognized advantages of cellulose-based polymers, namely lubricity and consistency enhancement, provide the ‘suggestion’ sufficient to motivate the art worker to substitute them for Bluard’s aluminum octoate.”) Such reliance is akin to “hindsight reconstruction.” *Id.* Thus, in spite of Furse’s short exposition on the advantages of using an evacuated tube for containing blood generally, Furse does not suggest or motivate the use of an evacuated tube in a method of detecting a target analyte. Applicants respectfully assert that the Examiner has not established a *prima facie* case of obviousness and request that the Examiner withdraw the rejection.

**Double Patenting Rejection**

Claims 1 and 5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1, 2, and 13 of Duong (U.S. Patent No. 6,740,518 B1) in view of Rubinstein (U.S. Patent No. 5,108,573).

In making an obviousness-type rejection, the Examiner can cite only analogous prior art. Applicants assert that Rubinstein is not analogous prior art. First, the Patent Office's classification of the references is evidence in determining their nonanalogous. *In re Ellis*, 476 F.2d 1370, 1372 (CCPA 1973). The Patent Office has assigned Rubinstein to class 204, whose rubric is "Chemistry: Electrical and Wave Energy", while the Office has assigned Duong to class 435, "Chemistry: Molecular Biology and Microbiology." Rubinstein thus addresses the electromagnetic properties of matter, a distinct and nonanalogous field of inquiry in comparison to the biologically significant molecules addressed by Duong. Second, a reference is from a nonanalogous field if the reference is not reasonably pertinent to the particular problem with which the present invention is concerned. See *In re Clay*, 966 F.2d, 656, 659 (Fed. Cir. 1992). Rubinstein teaches that the self-assembled monolayers is selected to "lower the energy of polymer/substrate interactions" and thus to "render[] the surface 'polymerophilic.'" Rubinstein, col. 2, ll. 31-35. On the other hand, the purpose of self-assembled monolayers in the instant application is "providing the benefits of shielding the electrode from solution components and reducing the amount of non-specific binding to the electrodes." Specification, p. 13, ll. 16-18. Self-assembled monolayers facilitate polymer binding in Rubinstein, while they hinder polymer binding in the present invention. Rubinstein is therefore not pertinent to the problems addressed by the instant application and is not analogous art.

The Examiner relies on the specification of Duong to contend that because Duong teaches a circuit board that is in an injection molded sample chamber, claim 1 of Duong

discloses the use of a tissue collection device. However, the Examiner is respectfully reminded that “[w]hen considering whether the invention defined in the claim of an application is an obvious variation of the invention defined in the claims of a patent, the disclosure of the patent may not be used as prior art.” MPEP § 804II(B)(1). The issue in a nonstatutory double patenting rejection is “whether the differences in subject matter between the two *claims* render the *claims* patentably distinct.” *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001) (emphasis added). By referring to the injection molded sample chamber, the Examiner improperly relies on the disclosure of Duong. In effect, the Examiner is attempting to import limitations from the specification into the claims of Duong since claim 1 of Duong could be infringed by practicing the method through use of an array not in an injection molded sample chamber. The court in *In re Vogel*, 422 F.2d 438, 441 (CCPA 1970), stated that “the words in a claim are generally not limited in their meaning by what is shown in the disclosure.” Because the claims in Duong do not teach a tissue collection device, Duong, even in combination with Rubinstein, does not teach all the limitations of amended claim 1 of the instant application.

The Examiner cites the specification of Rubinstein to find motivation to combine a self-assembled monolayer with an array complex to form the method recited in claim 1. As stated above, for a nonstatutory double patenting rejection, the Examiner must look to the claims of the references, not to the specification, in determining *prima facie* obviousness. In reciting the teaching of Rubinstein that incorporation of a self-assembled monolayer on a metal electrode would facilitate and regulate the bonding between the modified metal surface of the electrode and a conducting polymer, the Examiner has improperly referred to the specification of Rubinstein. The Examiner has not found suggestion or motivation to combine in the claims of

Duong or Rubinstein, separately or in combination, and thus has not established a *prima facie* case for obviousness.

The Duong and Rubinstein references are classified in nonanalogous arts. Furthermore, neither all the limitations of amended claim 1 nor the motivation to combine are found in the cited references separately or in combination. For these reasons, Applicants respectfully request the withdrawal of the Examiner's double patenting rejection.

**CONCLUSION**

Applicants respectfully submit that the claims are now in condition for allowance and early notification to that effect is respectfully requested. If the Examiner feels there are further unresolved issues, the Examiner is respectfully requested to phone the undersigned at (415) 781-1989.

Respectfully submitted,  
DORSEY & WHITNEY LLP

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